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510(k) Summary

Submitted by:	dj Orthopedics, LLC 2985 Scott Street Vista, CA 92083-8339 U.S.A. Tel: (760) 734-3122 Fax: (760) 734-5544
Date:	May 24, 2002
Submitted by:	Nora C.R. York, Regulatory Affairs Manager
Trade Name:	Alaron Surgical Active Knee® System
Classification Name:	Prosthesis, knee joint, patellofemorotibial, polymer/metal /polymer semi-constrained cemented prosthesis - 888.3560 (87JWH)
Common/Usual Name:	Knee Prosthesis, Partially Constrained

Substantially Equivalence:

The Active Knee® System is substantially equivalent to the Sulzer Orthopedics Natural-Knee II Constrained Knee System, K973412.

Product Description:

Device System

The Active Knee System is a modular knee system consisting of a femoral component, a standard meniscal insert, an ultracongruent meniscal insert (tibial insert), a patella, and a tibial baseplate.

Femoral Component

The femoral component is an anatomic, asymmetrically designed prosthesis manufactured from cast cobalt chromium/molybdenum (ASTM F75). The condylar prosthesis was designed for optimal weight transmission and flexion as well as giving maximum contact area to reduce material stress on the meniscal insert. The design incorporates a trochlear groove, which conforms to the geometry of the patellar prosthesis and allows for sliding articulation. From the medial/lateral view, the condylar geometry has a radial inward and upward sweep in the coronal plane, which assists in maximizing the contact area.

sweep in the coronal plane, which assists in maximizing the contact area. Anterior and posterior cuts are not parallel. There is a two (2) degree flaring, encouraging loading distally.

The interior box of the cemented femur is designed with a recess into the distal end of the prosthesis to enhance polymethylmethacrylate (PMMA) fixation.

The femoral components are available in seven (7) sizes: small medium, regular-narrow, regular, large-narrow and extra large in both a right and left implant.

Tibial Baseplates

The tibial baseplates are symmetrical . The baseplates are manufactured from grit-blasted cobalt chromium/molybdenum (ASTM F75). The baseplates are available in ten (10) sizes, small, medium, regular, large and extra-large, in both a narrow and a wide version.

The inferior surface of the tibial baseplate is grit blasted to further enhance cement fixation. A central keel on the inferior surface allows for insertion onto the tibia.

Standard Meniscal Insert (Tibial Insert)

The standard meniscal insert is symmetrical and available in seven (7) sizes, small, medium, regular, regular narrow, large, large narrow, extra-large, of five (5) different thickness of each (6mm, 7.5mm, 9.5mm, 11.5mm, 13.5mm). The minimum polyethylene thickness is 6mm. The meniscal insert is designed with a clip-on mechanism on the underside to secure a firm seat in the capture feature of the tibial tray.

The standard meniscal insert is a semi-constrained condylar design and is manufactured from Ultra-High Molecular Weight Polyethylene (UHMWPe, ASTM F-468). Additional posterior stability can be provided utilizing the ultracongruent meniscal insert, which is designed with an anterior lip.

Patella

The patella has a dome shape with the reverse curvature of the femoral condyles. The patello-femoral geometry consists of a deep trochlear groove for complete articular conformity. The patella is designed with three (3) small stems for fixation with PMMA cement. The patella is available in five sizes, small, medium, regular, large, and extra-large.

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Intended Use/Indications for Use:

The Active Knee® System is indicated to be used only with bone cement in patients suffering from the following conditions:

- Noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis.
- Inflammatory degenerative joint disease including rheumatoid arthritis.
- Correction of functional deformity such as varus, valgus, or flexion deformities.
- Revision procedures where other treatments or devices have failed.
- Treatment of fractures that are unmanageable using other techniques.

The device is intended for single use only.

The Active Knee® System is contraindicated for the following conditions:

- Acute or chronic infections, either local or systemic;
- Severe muscular, nervous or vascular disease endangering the leg;
- Defective bone structures, which could impede adequate anchoring of the implant;
- Patients who are younger than 60 years whose joint disease is such that good results may be achieved by using other reconstructive procedures such as osteotomy and;
- All associated diseases which could endanger the function and success of the implant.

Performance Testing:

Performance testing was conducted for the Active Knee System as recommended by the FDA Draft Guidance for the Preparation of Premarket Notifications 510(k)s for Cemented, Semi-Constrained Total Knee Prosthesis dated April 1993 and updated on December 8, 1998. The testing was conducted for the femoral, tibial baseplate, standard meniscal insert, ultracongruent meniscal insert (posterior stabilizer) and the patella prostheses. Testing consisted of range of motion and constraint (stability characteristics), surface roughness characteristics, contact areas and surface stress, resistance to lateral subluxation and fatigue strength.

When compared to other contemporary knee designs, the Active Knee System demonstrated similar performance characteristics.

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Bio-compatibility:

The Active Knee® System is made of materials for surgical implant applications. The materials used for the implants are ASTM F75 Specifications for Cast Cobalt-Chromium-Molybdenum Alloy for Surgical Implant Applications and ASTM F648 Specifications for Ultra-High Molecular Weight Polyethylene Powder and Fabricated Form for Surgical Implants.

Sterilization:

- Metal implants are sterilized with 25 to 42 kGy (2.5 to 4.2 Mrad) gamma radiation per ISO 11137.
- Polyethylene implants are sterilized with Ethylene Oxide per EN 550.

Conclusion:

The performance testing demonstrated that the Active Knee® System is substantially equivalent to the Sulzer Orthopedics Natural-Knee II Constrained Knee System, K973412 and other similar marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 23 2002

Ms. Nora C. R. York
Regulatory Affairs Manager
dj Orthopedics, LLC
2985 Scott Street
Vista, California 92083-8339

Re: K021740
Trade/Device Name: Alaron Surgical Active Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH
Dated: August 30, 2002
Received: September 3, 2002

Dear Ms. York:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K021740

Device Name: Alaron Surgical Active Knee® System

Indications For Use:

The Alaron Surgical Active Knee® System is semi-constrained and is intended to be used only with bone cement in patients suffering from the following conditions:

- Non-inflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis.
- Inflammatory degenerative joint disease including rheumatoid arthritis.
- Correction of functional deformity such as varus, valgus, or flexion deformities.
- Revision procedures where other treatments or devices have failed.
- Treatment of fractures that are unmanageable using other techniques.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021740

(Optional Format (3-10-98)